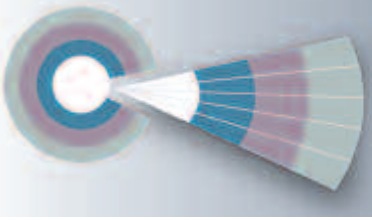


Developing the Right Product, the Right Way, at the Right Time

> *"Innovation is not the product of logical thought, although the result is tied to logical structure."*
> Albert Einstein

Product Research and Development (R&D) is critical to your business and competitive ability. It represents the life's blood of future business success. Investing in the creation of a new product is a high-risk activity, and success is rare. Even rarer is the successful development of a product that fundamentally changes the value proposition within a therapeutic category. Such new product investments, fraught with regulatory compliance pitfalls from concept to delivery, require deep financial commitment.

Economic and industry cycles set the context for the importance of innovation, and therefore of Product R&D. In fast-growing market sectors, product change is part of the competitive race, and significant investments are made in Product R&D. In mature markets, where growth has slowed, investors rely on Product R&D to assess the organization's future potential. New product developments can help slow the rate of genericization and protect margin erosion.

In these mature market sectors, new developments are likely to be incremental, and small advantages can differentiate a leader from less successful followers. Product R&D delivers a pipeline of new products that determine the organization's future financial performance and signify confidence in the future of the business. Three significant barriers prevent it from delivering the required product changes in the most effective way.

Barrier 1: ***Lack of information to determine strategy requirements***

Product R&D embraces risk. The odds are stacked against continual success, especially if the business expects a BIG new product idea. Companies typically define Product Development success by sales or profit growth and the ROI expected within a given time period. Measuring financial performance is vital, but interpreting success too rigidly may lead the company to miss innovation

opportunities. It is better to define and measure drivers and development milestones that affect the pipeline of new products. Similar to a portfolio investment strategy, these metrics allow for more opportunities (and therefore more failures), but let you know when to "fail fast" to satisfy the overarching profit or growth goal. Only a few product initiatives make it through to the final development stage.

You can tolerate a calculated and controlled percentage of failure if the overall portfolio of new product developments is financially successful. You may employ other aspects of portfolio investment strategy to determine your investment risk profile. How much money should you invest in new product development for low, medium and high-risk ideas? Every company is looking for the next "blockbuster" drug, but with $1 billion as an average for bringing a new drug to market from research through to regulatory approval, the benefit must be apparent. Investment in incremental product development ideas is safer, as well as being crucial. Such investment will better match the current product range and serve the dual purpose of protecting the existing business while extending the product proposition beyond what is currently offered.

Determining the right mix requires that Product R&D benefit from insights into markets and customers. This means knowing what product attributes and price points could shift prescribing and purchasing behavior, and understanding the operational costs and production implications of these. Only by integrating all these business inputs and information sweet spots can you achieve a well-developed new product proposition.

Barrier 2: ***Product R&D lacks the integrated business process information needed to develop targeted, comprehensive product offerings***

Product R&D decisions affect and rely on Marketing, Sales, Finance, Operations, Regulatory and Legal Affairs and other business departments. Without appropriate visibility, departmental barriers may get in the way and stymie the product development process. For example, current regulations may strongly inhibit the development of certain drug categories or significantly affect the direction of development. By monitoring the appropriate performance drivers, combined with appropriate incentives, you can improve the R&D process from idea generation to alignment on priorities to engaging Finance to ensuring approval, so the value of new products is understood and forecast.

Barrier 3: ***Inability to measure and analyze the drivers of R&D success***

New product pipelines depend on timely action. Speed to market paired with insight from "fast failures" is more important than perfection and indecision. Risk is part of the drug discovery and development process. "Calculated" failures are not necessarily negative; they may actually assist the development process. Failures can become stepping stones toward success. Product R&D must understand what drives success and failure.

No amount of laboratory work, adherence to regulation, pre-clinical trials or clinical trials guarantees success. Making the "go or no go" decision requires information sweet spots to allow the business to decide whether it needs more resources to improve the new offering, or if the cost of delay—either in lost revenue or lost competitive advantage—means the product must launch now.

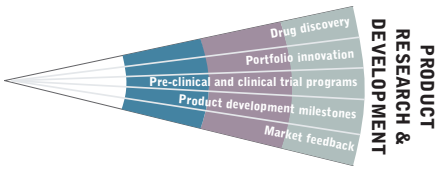
Often it is not the business that makes the "go or no go" decision, but a regulatory body that approves the product or denies it approval. Within this process, it is important for a company to know the factors within its control that contributed to approval or rejection.

From a Gamble to Controlled Product and Portfolio Development

Product R&D combines many cross-functional requirements, balances risk, learns from failures, and then generates a pipeline of timely new products. Accurate information is a key enabler of this process.

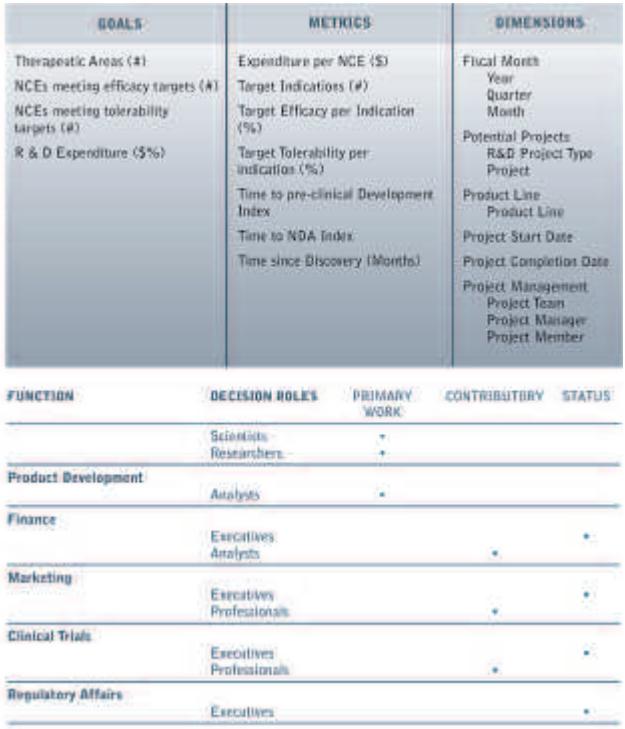
The Product R&D process combines five key decision areas with associated information sweet spots:

- **Drug discovery** ➔ What new chemical entities are feasible to develop with what chances of success?
- **Portfolio innovation** ➔ Which gaps in the product portfolio are addressable with the available resources, and what are the associated risks?
- **Pre-clinical and clinical trial programs** ➔ What is the optimal level of investment in trials and for what new chemical entities?
- **Product development milestones** ➔ How do we manage priorities and timings, ensure compliance and monitor risks as they change during the development process?
- **Market feedback** ➔ What external verification process will enhance and confirm new product development opportunities?



Drug Discovery

Drug discovery is such an important area for many life sciences companies, involving sophisticated high-level research, that it is sometimes given "special status" with goals and metrics removed from the rest of the business. Yet drug discovery is the engine of R&D-driven pharmaceutical companies, and its process data has to be integrated with those from other decision areas if the business is to excel in performance. It is well-known that the failure rate in drug discovery is high—only around one in fifty new compounds ever makes it from the laboratory to a Phase III clinical trial—and it is those failures that push up the cost of R&D. Therefore, managing failure efficiently is as important as managing and accelerating successes. Ensuring visibility into this process for senior management is crucial. Information flows that help to speed up the process of drug discovery and pre-clinical research are similarly important; once a patent is granted, every month that a new product's route to market is delayed shortens the period during which it can earn the profits required to meet its ROI criteria, and such delays ultimately work against the financial targets of the business.



GOALS	METRICS	DIMENSIONS
Therapeutic Areas (#) NCEs meeting efficacy targets (#) NCEs meeting tolerability targets (#) R & D Expenditure ($%)	Expenditure per NCE ($) Target Indications (#) Target Efficacy per Indication (%) Target Tolerability per indication (%) Time to pre-clinical Development Index Time to NDA Index Time since Discovery (Months)	Fiscal Month Year Quarter Month Potential Projects R&D Project Type Project Product Line Product Line Project Start Date Project Completion Date Project Management Project Team Project Manager Project Member

FUNCTION	DECISION ROLES	PRIMARY WORK	CONTRIBUTORY	STATUS
	Scientists	•		
	Researchers	•		
Product Development				
	Analysts	•		
Finance				
	Executives			•
	Analysts		•	
Marketing				
	Executives			•
	Professionals		•	
Clinical Trials				
	Executives			•
	Professionals		•	
Regulatory Affairs				
	Executives			•

Portfolio Innovation

The portfolio innovation decision area takes potential opportunities identified by the research team and examines the practicalities in more depth. This decision area answers questions about the costs and benefits of developing new products or new product attributes to fill portfolio gaps, and how achievable these developments are given available resources and the risk of failure. Some may only be achievable through licensing new technology from third parties.

Innovation runs the gamut from incremental improvements to significant product "revolutions." Incremental developments include drug delivery and packaging changes, minor formulation improvements and brand extensions. These developments are usually intended to fill gaps in the product portfolio. For instance, by making the product more convenient to use, and increasing the price, the business may extend its offering into a profitable new segment. At the high-risk end of innovation, you must measure time to market, implementation difficulty, compliance difficulty, external market or technical shifts, future scenario values, and estimated ROI. These metrics also help you prioritize threats and opportunities. For example, classifying R&D activities into life-cycle categories balances short-term and long-term priorities. Measuring the difficulty of implementation ensures you don't choose impractical blue-sky projects at the expense of what's needed in the short term. Future scenario valuations with estimates of the upper and lower limits of potential sales and profits set the size of a project. ROI looks at the whole picture by including upfront investment, operating costs and sales.

As a decision area, portfolio innovation recommends which opportunities are right for the business by aligning with other departments, particularly Marketing.

PRODUCT/PORTFOLIO INNOVATION

GOALS	METRICS	DIMENSIONS
New Product Market Share (%) New Product Sales ($) Product Develop. Cost ($)	Sales at Peak Index New Product Achievability Score/Risk (#) New Product Breakeven Time ($) New Product Sales Potential ($) New Products Developed (#) New Products in Market ($/%) Project Resource Days – Plan Project Cost – Plan ($)	Fiscal Month Year Quarter Month Potential Projects R&D Project Type Project Product Line Product Line Project Start Date Year Quarter Month Project Start Date Project Management Project Team Project Manager Project Member Project Completion Date Year Quarter Month Project Finish Date

FUNCTION	DECISION ROLES	PRIMARY WORK	CONTRIBUTORY	STATUS
Product Development				
	Executives	•		
	Managers	•		
	Analysts	•		
	Professionals	•		
Finance				
	Executives			•
	Analysts		•	
Marketing				
	Executives			•
	Analysts		•	
Sales				
	Executives			•
	Analysts		•	
Customer Service				
	Executives			•
	Analysts		•	
Operations / Production				
	Executives			•
	Analysts		•	

Pre-Clinical and Clinical Trial Programs

Regardless of the origin of a product innovation—in-house drug discovery, licensing-in from a third party or incremental improvement to an existing product—it is likely that it will be required to undergo some form of clinical trial program. The data from such programs that support a product's safety and efficacy is essential for regulatory approval, which in turn is a pre-requisite for marketing of the product. Yet the regulatory affairs team and the marketing team are sometimes kept in the dark until a trial program is nearing completion.

There is also the important question of how much investment and activity is going on in clinical trials and how it can be properly tracked. This tracking embraces the status of clinical trials—which ones have received protocol approval, which have initiated subject enrollment, which are not meeting their enrollment requirements, which have completed enrollment and which have generated interim or final results. This is a key element in making the product pipeline more visible and more integrated with the rest of the business and in enabling action to take place if a program is not going according to plan. But it also has to embrace the forecasting, planning and management of clinical trial expenditure; with Phase III trials often costing in excess of $100 million, this is a critical decision area financially as well as strategically. Clinical trial

GOALS	METRICS	DIMENSIONS
Protocol Approval Completion Index	Time to protocol approval (months)	Fiscal Month
Enrollment Completion Index	Enrollment Rates versus Plan (%)	Year
Trial Completion Index by Phase	Site Performance Index	Quarter
Trials cost ($)	Site Costs to Completion ($)	Month
	Reported Efficacy per Indication (%)	Potential Projects
	Reported Tolerability per Indication (%)	R&D Project Type
	Trial Completion – Actual by Phase (%)	Project
	Approval Completion – Plan by Phase (%)	Product Line
	Total Site Costs ($)	Product Line
	Investigator Fees ($)	Project Start Date
	Clinical Lab Fees ($)	Project Completion Date
	Consultant Expenses ($)	Project Management
	Recruitment Expenses ($)	Project Team
		Project Manager
		Project Member
		Therapeutic Indication
		Product Comparator(s)

FUNCTION	DECISION ROLES	PRIMARY WORK	CONTRIBUTORY	STATUS
Clinical Trials				
	Managers	•		
	Analysts	•		
	Professionals	•		
Finance				
	Executives			•
	Analysts		•	
Marketing				
	Executives			•
	Professionals		•	
Sales				
	Executives			•
	Professionals		•	
Regulatory Affairs				
	Executives			•
	Analysts		•	
Contract Research Organization				
	Executives			•
	Professionals		•	

expenditure tracking increasingly has to be done through an activity-based approach that matches expenses to activities, rather than a time-based accrual approach which suffers from an inherent latency in the billing process and does not take account of the increasing complexity of clinical trial programs.

"Data analysis used to come from two analysts in the finance area, which created a funnel effect. This was a source of tension because clinical people couldn't do anything until finance had the numbers."

Kevin Murphy, CFO, Middletown Regional Hospital

Product Development Milestones

This decision area is used to project manage the development pipeline process. It establishes milestones, manages and adjusts priorities and timings, and monitors risks as they change. This is key to effective project management of the huge investments that life sciences companies make in product development, and it is central to the forecasting of resource requirements for regulatory submissions. Achievement of development milestones also sends extremely important signals to financial analysts and the external investment community.

In today's competitive environment where speed to market is key to success, pharmaceutical companies are under constant pressure to project manage the drug development process effectively. In practical terms, this implies managing several aspects at once, such as the efficiency, cost-effectiveness and cost containment of the clinical trial process and, if successful, bringing the drug to market quickly. To do so requires leveraging available technologies, fulfilling regulatory requirements, managing the organization's capabilities and business processes, as well as aligning executive information needs to pass given decision milestones. Without strong and effective project management capabilities, potential financial rewards are put at risk.

Key sections of the pipeline and the progress of potential new products through pre-clinical and clinical trials have to be visible internally, and often externally as well. This visibility is difficult to achieve, given the complexity of clinical trials and the number of contracts in place, and the industry has very limited tools—typically, spreadsheets and manual processes—for tracking and predicting this expense. However, with the soaring cost of clinical trials, the need for management visibility is critical. A single study can cost several pennies to the earnings per share (EPS) of even the largest pharmaceutical company. And failure to meet a trial milestone can have catastrophic impacts for the study sponsor; in a recent example, a pharmaceutical company's failure to meet a study endpoint resulted in a stock crash of 40% on the news.

Many companies then use Stage-Gate® or phase-gate processes that complement and follow on from the trials. Less formal processes still require that you answer questions such as: *What new product development ideas do we have? What is the scale of the identified opportunity? Do we have the skills in-house to take this idea to market? What are the risks? Is the opportunity aligned with our strategic priorities? What are the likely financial rewards?*

Measuring performance milestones is critical to this decision area. Of the number of preliminary initiatives, how many milestones are passed before rejection, and why? The number of products ready for commercialization tells you about projects and how they pass through the process. Logging and evaluating the reasons for success or failure through these milestones will help you improve your Product R&D process. Regular planning and gap analysis reviews anchor the development process with business priorities and help "identify failure early." In practical terms, if a sponsor can identify a product as a risk in Phase 1, it can save tens of millions of dollars by "killing" the product before it enters Phase 3.

Without this focus and monitoring, the process may be sidelined by day-to-day concerns. It is critically important to ensure the success of all phases, from development to approval and full commercialization. Information that focuses and fine-tunes each stage, and provides incentives, is imperative to ensuring successful product launches.

PRODUCT DEVELOPMENT MILESTONES

GOALS	METRICS	DIMENSIONS
Time to Market Index Product Develop. Cost ($)	Pre-clinical/NCEs discovered (%) Pre-Clinical Completion Index Pre-Clinical Completion (%) Trial Completion Index by Phase NCE Failures at Pre-Clinical Stage (#) NCE Failures at Clinical Phase 1 (#) NCE Failures at Clinical Phase 2 (#) NCE Failures at Clinical Phase 3 (#)	Fiscal Month Year Quarter Month Forecast Scenario (Plan/Actual/Forecast) Scenario Product Development Milestone Product Line Product Line Project Project/Program Type Project Project Start Date Year Quarter Month Project Finish Date Project Management Project Team Project Manager Project Member Project Completion Date Year Quarter Month Project Finish Date

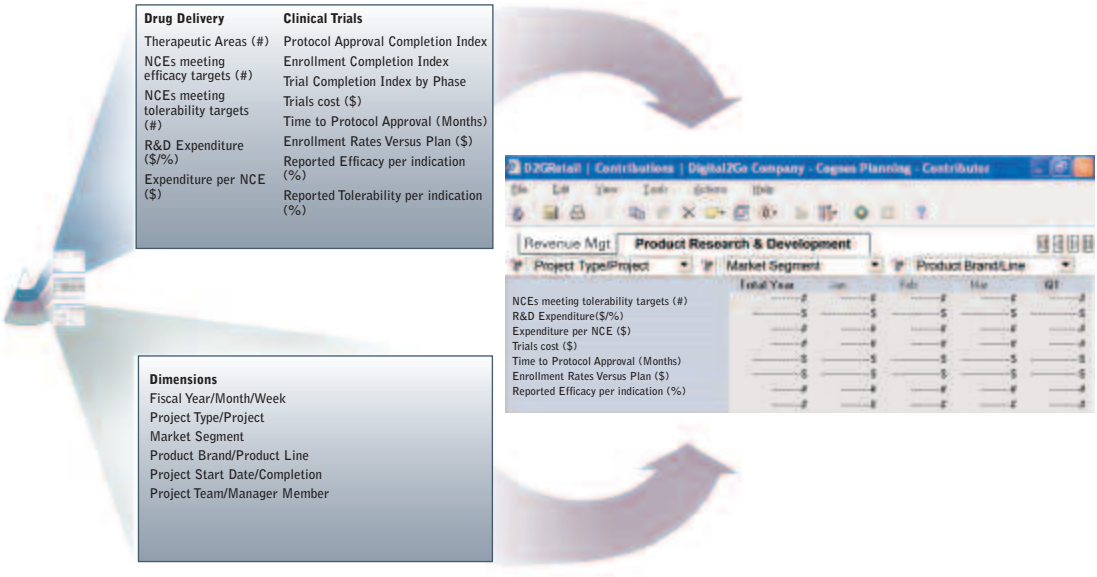
FUNCTION	DECISION ROLES	PRIMARY WORK	CONTRIBUTORY	STATUS
Product Development				
	Executives	•		
	Managers	•		
	Analysts	•		
	Professionals	•		
Finance				
	Analysts		•	
Marketing				
	Analysts		•	
Sales				
	Analysts		•	
Operations / Production				
	Analysts		•	

Market Feedback

The market feedback decision area combines an external reality check with internal understanding of development opportunities and requirements. It is an extension of a product and portfolio gap analysis, generating external insights to use in gap assessment. There are many examples of overly engineered products that fail because they do not balance costs and those features actually valued by customers. Market feedback and external verification as part of the development process are essential for success. The insights these activities produce let the organization understand what investments are necessary for new product attributes and determine if the business can afford them. In some cases, it may make sense to pull out of an opportunity area rather than make investments with an insufficient chance of payback. An information framework that uses this data can support and confirm Product R&D decisions. This decision area is also a tool for creating cross-functional alignment and internal commitment to new product commercialization.

GOALS	METRICS	DIMENSIONS
Suggestion Cost ($) Suggestion Value-Added Score (#) Customer Satisfaction Score	Customer Feedback Count # Comments / Suggestions (#) Product Awareness Score (#) Implementation Difficulty Score (#)	Fiscal Month Year Quarter Month Marketing Segment Market Segment Micro-Segment Product SKU Product Line Brand SKU Suggestion Priority Index Suggestion Type

FUNCTION	DECISION ROLES	PRIMARY WORK	CONTRIBUTORY	STATUS
Product Development				
	Executives	•		
	Managers	•		
	Analysts	•		
	Professionals	•		
Customer Service				
	Executives			•
	Managers		•	
	Analysts		•	
Sales				
	Executives			•
	Analysts		•	
Marketing				
	Executives			•
	Analysts		•	



The Drug Delivery and Clinical Trials decision areas illustrate how the Product Research & Development function can monitor its performance, allocate resources and set plans for financial and operational targets.